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NORTH CAROLINA CHAPTER

SOCIETY OF QUALITY ASSURANCE

P.O. Box 14274 ■ Research Triangle Park ■ NC 27709

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
1200 Pennsylvania Avenue NW
Washington DC 20460

Attn: Docket Number EC-2000-007

Re: North Carolina Chapter of Society of Quality Assurance (NCCSQA) Comments

Dear Sir/Madam

The North Carolina Chapter of the Society of Quality Assurance (NCCSQA), in concordance with its membership and the Society of Quality Assurance (SQA) is pleased to add comment to the CROMERRR proposed rule as published in 66 Federal Register 46162 (August 31, 2001). This document is listed as 40CFR Parts 3, 51, et al. "Establishment of Electronic Reporting: Electronic Records; Proposed Rule."

NCCSQA, along with SQA, is composed of quality assurance professionals who support work that is conducted according to Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Manufacturing Practices (GMPs). Since EPA GLP programs are among the Code of Federal Regulations Title 40 programs which are subject to CROMERRR, NCCSQA member companies are impacted by the Agency's Proposed CROMERR Rule.

NCCSQA welcomes efforts of the EPA to move in a direction that enables electronic reporting and record-keeping. However, NCCSQA believes the Proposed Rule, as NCCSQA interprets it, will pose an undue financial and resource burdens on the regulated community that are not accurately articulated in the CROMERRR Preamble, Proposed Rule.

Enclosed with this letter, NCCSQA respectfully submits comment regarding NCCSQA's understanding of 40 CFR Parts 3, 51, et al., "Establishment of Electronic Reporting: Electronic Records; Proposed Rule."

Sincerely,

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Issues and Methods Committee
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Summary:

In 1998, Congress passed the Government Paperwork Elimination Act, (GPEA) Public Law 105-277, which requires that agencies be prepared to allow electronic reporting and recordkeeping under their regulatory programs by October 21, 2003. On August 31, 2001, EPA published its response to the GPEA, the Cross Media Electronic Reporting and Recordkeeping Rule (CROMERRR) Proposed Rule. In this document, the EPA has directed that all programs and entities under Title 40 of the Code of Federal Regulations (CFR) be subject to the new regulations proposed in CROMERRR if they choose to report and to keep records electronically.

NCCSQA wishes to comment on the following major points of the CROMERRR Proposed Rule:

1. The EPA maintains that CROMERRR is a "purely" voluntary rule, wherein only entities that choose to report and maintain electronic records under Title 40 may do so. We submit that, based on current practices, maintaining electronic records is anything but voluntary. Under the current FIFRA and TSCA regulations, electronic recordkeeping is a fact and that reverting to paper records is impossible given the scope of present day equipment and instrumentation.

2. The stringent criteria for maintaining electronic records in a 'one size fits all' manner, whereby all electronic records maintained for the purposes of meeting Title 40 program requirements must meet the same criteria, whether an environmental monitoring system, a toxicology data collection system, a policy record, or an indexing tool, imposes added cost and burden to regulated entities, rather than removing obstacles to electronic record-keeping.

3. The costs for implementing and maintaining electronic recordkeeping systems were woefully underreported in the proposed rule. EPA also has vastly underestimated the number of entities that would have to comply with CROMERRR, thereby compounding the costs' effects to industry and the economy.

4. The proposed rule adds language that "raises the bar" for requirements to maintain electronic records due to a perceived vulnerability in that electronic records are more easily subject to manipulation and fraud unless stringent security measures are employed. Fraud can be perpetrated just as easily electronically as it can be on paper, regardless of the controls put in place.

5. Due to the extensive record retention requirements of some EPA programs, the rapid changes in technologies could impose an extremely challenging burden on industry to find cost beneficial solutions to maintaining these records for the record retention period, which may exceed 50 years or more.

Comment

NCCSQA's primary comment to the EPA is that we believe the recordkeeping and reporting portions of the CROMERRR Proposed rule should be separated and each be re-evaluated at this time. While recordkeeping is the area where we have devoted most of our effort in providing comment, we feel that both the record-keeping and the reporting portions have significant issues and associated costs that have not been clearly investigated or articulated. Under the current proposal, the discrepancies between what the rule says versus the realities of (i) how extensively electronic reporting and recordkeeping are used now and (ii) how it would apply to those practices, are too far apart for the rule to be of value. There is growing concern that CROMERRR would also have an adverse impact on existing state e-record reporting systems, of which many of our members currently use.

The EPA should take the steps to re-evaluate the rule for now and begin a new process of information gathering, including the assembly of several EPA/industry working groups to focus on the current applications of electronic records and what solutions may be possible for both recordkeeping and reporting options. If the EPA does not take these steps at this time, we believe at the very minimum, the rule should be separated into two parts, electronic reporting and electronic recordkeeping. Then the electronic recordkeeping portion can be withdrawn until further discussions can take place.

It is understood that electronic reporting is required and necessary and that the agency is under pressure from the GPEA to ensure the availability of electronic reporting by October 2003. Electronic recordkeeping is the bigger issue here, and due to time constraints for comments, we are not prepared to comment on the reporting aspects of the proposed rule. For the FIFRA and TSCA programs, our members are still prepared to submit reports via paper or magnetic media, which is exempt from the CROMERRR rule.

Electronic recordkeeping is the part of the rule that causes the most concern among our members. From discussions with the EPA at various public hearings, it has become obvious that the true effect of the rule was not studied by the EPA concerning electronic recordkeeping as much as it was concerning electronic reporting. Industry after industry has now come forth and described the extent of computer recordkeeping throughout the regulated community, and it has no comparison to what the agency originally had determined.

Throughout the proposed rule there are statements that indicate that the rule is voluntary. Entities may choose to report and keep electronic records if they wish, following that the agency publishes in the Federal Register each time that a program becomes ready to accept and allow electronic reporting and recordkeeping. What this overlooks is the fact that these entities have been collecting electronic records for years, and, in some cases, are now already reporting electronically to the EPA or state agency. Within FIFRA, raw data is collected by electronic instruments such as gas chromatographs, mass spectrometers, etc. All of these instruments collect the data into electronic files, which is then reviewed and printed out. The print out is considered the official raw data, and is archived with the study. The instruments all have validation to ensure they are operating properly, but the electronic record is stored for only a short time period. CROMERRR would drastically change this process, discounting the printout and forcing the facility to maintain the electronic file instead, often for an

extremely long time period. It is unreasonable to think that the rule could be voluntary under these circumstances, as no entity could actually change their current processes from electronic back to paper, based on the definitions given in the rule.

In addition, CROMERRR states that the EPA program must publish in the Federal Register when it is ready to allow electronic recordkeeping and reporting. What would it mean for these regulated entities that now already collect e-records, when CROMERRR becomes final rule and the EPA program has not yet published that it is allowable for them to do so? Will they be out of compliance? The agency has stated that this was not the intent of the proposed rule, however, it is the perception based on the descriptions listed in the preamble.

Since all electronic files are treated equally under CROMERRR, many items that are now kept electronically would be subject to the stringent requirements of subpart C, proposed rule. Low level risk e-records, such as master study schedules, SOPs, training records, etc, would all be forced into CROMERRR compliance since they are required by Title 40. It was suggested by the EPA, that we, the regulated community, might offer suggestions as to how to discern between high level and low level risk e-records. We suggest that the agency should look harder at the scope of this new rule and what it will require the regulated community, who already uses an abundance of e-records, to do to be in compliance. Then the electronic recordkeeping rule can be crafted to allow for discrepancy when accommodating high vs low level risk e-records.

Also, this will require a rigorous programming effort by the regulated community to bring each and every one of their recordkeeping systems up to compliance, since virtually none of the standard software packages in use today have all of the necessary tools included as required in Subpart C, section 3.1. The question then becomes, whether or not this is in effect lifting the standards for electronic records over paper records so that electronic records would be deemed the most reliable form of a record. Why then does the agency feel that an electronic record, using 3.1 for compliance, would be any more secure and reliable than a paper record? We submit that electronic records can be manipulated and altered just as easily as a paper record even if the controls required by 3.1 are in place. To that extent the agency should rely on existing compliance and enforcement practices in place of increased electronic record requirements. At least a differentiation could be made between which e-records require the highest level of 3.1 vs. a possible lower level requirement. We also support the E-Sign legislation as an alternative to Subpart C, which is now broadly utilized to govern electronically created and maintained records.

EPA maintains that the costs for implementing CROMERRR would be a mere $40K the first year and $17K per year after, and only 467 facilities a year the first three years would choose to implement the rule. But after reviewing the requirements and discussing implementation with other companies, it could be assumed that the rule will affect at least 1.2 million facilities or programs within the US. Using the EPA's own numbers show that the cost effect to the economy is 48 billion dollars. That is money that must be found, budgeted and spent, to effect CROMERRR compliance. However, we challenge that the $40K average is inaccurate, considering several companies have estimated that bringing their existing instruments into compliance to be over $100K per instrument, not including the archiving costs. Several large companies have estimated the total cost of compliance for the proposed rule to reach 80-100 million dollars per company.

Finally, the FIFRA program has a virtual indefinite period under which record retention is required. If you apply this rule to e-records, as CROMERRR suggests, then the situation exists when technology changes that e-records will have to be migrated along to accommodate the changes. There would then be an increased risk that data from one system might not be completely formatted and migrated correctly into the new system, causing a breach in compliance. Since it is impossible to know what types of technologies will be available in the future it becomes very challenging for a regulated entity to manage what will be very large caches of data and records from system to system for an indefinite time period. However, the rule could be amended to allow for the transition or migration of the records from an electronic medium to a different medium, possibly even paper, should an existing system become obsolete. The OECD draft guidance document on electronic records has such a statement, whereby records can be migrated to a different medium should their equipment or software become technologically obsolete.

In conclusion, we believe that EPA does not fully understand the consequences behind the CROMERRR proposed rule, specifically the number of regulated entities directly affected and the extent that electronic records are currently used. CROMERRR should be separated into two distinct pieces - recordkeeping and reporting - and each be re-evaluated. New meetings need to be scheduled so that the regulated community can better communicate with the agency over the best way to move forward with electronic reporting and recordkeeping.

Sincerely,

Charles Reese
Issues and Methods Committee
NCCSQA